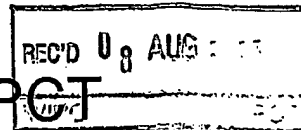


PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2005/000566

International filing date (day/month/year)
17.02.2005

Priority date (day/month/year)
17.02.2004

International Patent Classification (IPC) or both national classification and IPC
A61L15/60, A61L17/06, A61L27/22, A61L15/32

Applicant
ADVANCED PROTEIN SYSTEMS LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000566

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000566

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. -

because:

- ☒ the said international application, or the said claims Nos. 42-45,47,51-53,57-63 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for the whole application or for said claims Nos. -

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- ☐ has not been furnished

- ☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished

- ☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000566

Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	14-17,19,20,48,49
	No: Claims	1-13,18,21-47,50-63
Inventive step (IS)	Yes: Claims	
	No: Claims	1-63
Industrial applicability (IA)	Yes: Claims	1-41,46,48-50,54-56
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- The subject-matter of claims 42-45,47,51-53,57-63 is related to a method for treatment of the human or animal body from surgery or therapy. Using its discretion, the present authority decided not to carry out an internal preliminary examination on that subject-matter (Article 34(4)(a) PCT in conjunction with Rule 67.1(iv) PCT).

For the assessment of the present claims 42-45,47,51-53,57-63 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 - The following documents (D1-D4) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:

D1: US-A-5 733 563 (FORTIER ET AL) 31 March 1998 (1998-03-31)

D2: US 2003/211137 A1 (SIERRA DAVID) 13 November 2003 (2003-11-13)

D3: US-A-5 412 076 (GAGNIEU ET AL) 2 May 1995 (1995-05-02)

D4: EP-A-0 807 441 (NYCOMED IMAGING AS) 19 November 1997 (1997-11-19)

2. Novelty (Article 33(2) PCT)

- The subject-matter of present claims 1-13,18,21-47,50-63 is not new for the following reasons (Article 33(2) PCT):

- Document D1 (US5733563) describes a bioartificial hydrogel comprising a bifunctionalized polyethynene oxide, activated with an activating agent, and an albumin type protein. The bioartificial hydrogel may be used as dressing (Cf. D1, column 1, lines 10-16; column 4, lines 18-30; column 8, lines 54-60; claims 1-5,12).

The subject-matter described in document D1 takes away novelty of present claims 1,3-12,18,21,22,24-29.

- Document D2 (US2003211137) refers to a method of forming a wound dressing by reacting a protein polymer with a polyfunctional spacer or an activated derivative thereof (Cf. D2, page 1, paragraph 11; page 1, paragraph 17-page 2, paragraph 19; page 3, paragraph 32; page 3, paragraph 34-paragraph 37; claims 1-28).

The subject-matter described in document D2 takes away novelty of present claims 1-13,18,21-29,54-56.

- Document D3 (US5412076) describes a method of forming a protein polymer such as collagen by reacting a protein with a dicarboxylic acid or an activated derivative thereof (Cf. D3, column 1, lines 35-53; column 2, lines 21-48; column 4, lines 11-36; column 5, line 66-column 10, line 44; examples 10,11).

The subject-matter of document D3 takes away novelty of present claims 30,31,34-47,50-52,57-63.

- Document D4 (EP0807441) describes a contrast agent for use in diagnostic comprising a protein polymer and a polyfunctional spacer (Cf. D4, column 3, line 31-column 4, line 6; column 4, lines 30-56; column 5, lines 40-46; claims 1-15).

The subject-matter of document D4 takes away novelty of present claims 30-41,53,57-63.

3. Inventive Step (Article 33(1),(3) PCT)

a - Since the subject-matter of present claims 1-13,18,21-47,50-63 is known, obviously it can not involve an inventive step (Article 33(1),(3) PCT).

b - Although novel, the remaining subject-matter, which is the subject-matter of present claims 14-17,19,20,48,49 cannot be considered as being inventive for the following reasons (Article 33(1),(3) PCT):

- The problem to be solved by the present application is to provide a protein polymer gel suitable for topical administration as wound dressings.

- The solution proposed in the present application is method of forming a wound dressing as

described in present claim 1.

- Document D2 (US2003211137), which is considered as the closest prior art, refers to a method of forming a wound dressing by reacting a protein polymer with a polyfunctional spacer or an activated derivative thereof.
- The difference between the teaching of the closest prior art and the subject-matter of present claims 14-17,19,20,48,49 is merely the spacers and activating agents used and the conjugation of the protein polymer.
- The features described in present claims 14-17,19,20,48,49 are merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. Therefore, the subject-matter of present claims 14-17,19,20,48,49 is not considered as being inventive according to Article 33(1),(3) PCT.

Re Item VIII

Certain observations on the international application

- Present independent claim 38 does not refer to the proviso mentioned in independent claims 37. Therefore, claim 38 does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.